K132684
MAY 2 3 2014

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Communicating Imaging

510(k) Summary of Safety and Effectiveness

MEDWS

Product Name: MEDWS (variants MEDVIEW, MEDDIAG, MEDMAMMO)

Product Classification Name: Picture, Archive and Communications System

Product Code: LLZ

CFR Section: 892.2050

Classification Panel: Radiology device

Class: II

Date prepared: May 21st, 2014

Submitter's information (21 CFR 807.92(a)(1)):
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Name, title and phone number of contact (21 CFR 807.92(a)(1)):
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Predicate Device (21 CFR 807.92(a)(3)):
510k number: K103385
Regulation number: 892.2050
Device name: SecurView DX
Applicant: Hologic, Inc, 35 Crosby Drive, Bedford, MA 01730, USA
Classification product code: LLZ

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Device classification name: System, image processing, radiological
Class: II
Panel: Radiology Device

Device Description (21 CFR 807.92(a)(4)):

The MEDWS software range offers solutions for managing radiology images and reviewing them for diagnostic purposes. They are used in hospital or clinic radiology departments and in private medical imaging practices.
They are used by radiologists for all functions and by technicians for functions not involving diagnoses (formatting for printing, CD burning, etc.).
A solution from the MEDWS software range is installed on a computer connected to the imaging network. The radiology table (modality) manages image acquisition and sends images over the local network to a console from the MEDWS range.

Intended Use (21 CFR 807.92(a)(5)):

The MEDWS Software (MEDVIEW, MEDDIAG, MEDMAMMO) is intended for selection, display, manipulation and media interchange of medical images, including mammograms. It can show images from different modalities and interfaces to various image storage and printing devices using DICOM or similar interface standards.
Lossy compressed mammographic image are not intended for diagnostic review. Mammographic images should only be viewed with a monitor cleared by FDA for viewing mammographic images. For primary diagnosis, post process DICOM for presentation images must be used.
The MEDWS Software (MEDVIEW, MEDDIAG, MEDMAMMO) is typically used by trained professionals including but not limited to physicians, radiologists, nurses, medical technicians and assistants.

Technological Characteristics (21 CFR 807.92(a)(6)):

MEDWS is a software product used to manipulated digital medical images for diagnosis purpose. The device does not contact the patient, nor does it control any life sustaining devices.

MEDWS software runs under Windows XP Professional SP3 or Windows 7 operating systems for Pcs (as minimum and depending upon system configuration). The requirements on hardware are quite ordinary for a system for displaying images.

MEDWS has the same main technological characteristics as its predicate device.

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Non-clinical performance

The subject device is designed in conformance with:

- ACR/NEMA Digital Imaging Communication in Medicine (DICOM) Version 3.1
- ISO 15223-1:2012 - Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements
- ISO 14971:2007 - Medical devices - Application of risk management to medical devices
- IEC 62304:2006 - Medical device software - Software life-cycle processes
- IEC 62366:2007 - Medical devices - Application of usability engineering to medical devices

Every specification of the MEDWS software is validated by a bench test before release. Bench testing includes:

- The installation of the software
- The configuration of the software
- The management of the patient information
- The acquisition and integration of new data
- The manipulation of the data
- The DICOM conversion
- The DICOM connectivity
- The export and distribution of data

Substantial Equivalence

The design, fundamental technology, functionalities ,intended use and performances of the MEDWS software are similar and therefore substantially equivalent to its predicate like it is demonstrated in the table below.

	Predicate Device	Subject Device		If different, impact on safety or efficacy
		MEDVIEW MEDDIAG	MED-MAMMO	
Hardware requirements				
Operating system	Windows XP, Windows 7	Windows XP Professional SP3 or Windows 7		No difference
Memory	2.0 GB RAM	1.0 GB RAM	4.0 GB RAM	No impact : RAM needed is different in order to insure same efficacy
Processor	Dual	Pentium Core 2	Xeon Quad Core	No impact :

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	Predicate Device	Subject Device		If different, impact on safety or efficacy
		MEDVIEW MEDDIAG	MED-MAMMO	
	Processor Intel CPU with clock rate of 2.0 GHz or higher		3 GHz	Processor needed is different in order to insure same efficacy
Free disc space	Unknown	150 Mb for the software		No impact
Graphic Card	Unknown	OpenGL 2.0 compatible graphic controller (Chipset or graphic card)	256 Mo, OpenGL 3.0 compatible graphic card	No impact
Networking	Network Interface Card (NIC) 10/100 Base-T	100 Mbps TCP/IP network card	1 Gbps TCP/IP network card	No impact
Support conventional screen for multimodality image review	Yes	Yes	Yes	No difference
Support specific screen for mammography image review cleared by FDA		No	Yes	
Support Tactile screen	Unknown	No	Yes	Tactile screen does not add any safety risks because it permits better control by the user. There is no impact on efficacy.
Support Several screens at the same time	Yes	MEDVIEW : No MEDDIAG : Yes	Yes	No difference If needed, support of several screens is available in MEDDIAG or MEDMAMMO variants

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	Predicate Device	Subject Device		If different, impact on safety or efficacy
		MEDVIEW MEDDIAG	MED-MAMMO	
Support conventional Keyboard	Yes	Yes	Yes	No difference
Support specific keyboard for mammography image review		No	Yes	
Printing on DICOM printer	Yes	Yes		No difference
Printing on standard printer	Unknown	Yes		This functionality does not add risks and permit to user to keep some images in the paper patient file. There is no impact on safety.
Administration Setting				
Account user administration	Yes	Yes		No difference
Patients list administration	Yes	Yes		No difference
User preference setting	Yes	Yes		No difference
User workflow setting	Yes	Yes		No difference
DICOM Features				
Modalities supported	MG, MR, US, CT, SC, CR, PET, DR and multiframe mammography images	MG, MR, US, CT, SC, CR, PET, DR, ES, NM, PX, RF, XA and multiframe mammography images		The subject device support more modalities than the predicate device (ES, NM, PX, RF, XA). This has no impact on the safety of the device and permits to the device to be used for more patients.

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	Predicate Device	Subject Device		If different, impact on safety or efficacy
		MEDVIEW MEDDIAG	MED-MAMMO	
DICOM Objects transfer & communication	Yes	Yes		No difference
Query / retrieve DICOM Operation	Yes	Yes		No difference
Viewing DICOM Images	Yes	Yes		No difference
Viewing DICOM Reports	Yes	Yes		No difference
Send GSPS[1] or SC[2] images to other DICOM nodes	Yes	No, only SC images		GSPC is a file which contains parameters to apply to an image. The subject device could send the SC image, that is to say the image with the parameters applied. This difference has no impact on safety or efficacy of the device.
Exporting DICOM image	Yes	Yes		No difference
Exporting anonymised DICOM image	Yes	Yes		No difference
Exporting anonymised TIFF image	Yes	Yes		No difference
Application Synchronization and Data Exchange	Yes	Yes		No difference
Exporting anonymised TIFF image				
Windows / Level	Yes	Yes		No difference
Magnification Window	Yes	Yes		No difference

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	Predicate Device	Subject Device		If different, impact on safety or efficacy
		MEDVIEW MEDDIAG	MED-MAMMO	
Display at variable resolution	Yes	Yes		No difference
Rotation	Yes	Yes		No difference
Mirroring	Yes	Yes		No difference
Image inversion	Yes	Yes		No difference
Display of CAD results	Yes	No		Medical users are informed about this fact, and not all users use CAD, so this point does not add new risk.
Display of patient demographic information	Yes	Yes		No difference
Multiframe images breast MR CAD analysis And breast MR motion correction	Yes	No		The fact that MEDWS cannot perform MR CAD analysis and breast MR motion correction does not add new risks. Medical users are informed about this fact. Not all users use CAD nor display MR images.
Free hand drawing	Yes	Yes		No difference
Ellipse drawing	Yes	Yes		No difference
Ability to add textual annotation	Yes	Yes		No difference
Ability to	Yes	Yes		No difference

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	Predicate Device	Subject Device		If different, impact on safety or efficacy
		MEDVIEW MEDDIAG	MED-MAMMO	
measure features				
Other functions				
Image storage for short duration	Yes	Yes		No difference
Full conformance to IHE Mammography image profile	Yes	No		The transactions from IHE Mammography image profile not supported by MEDWS concern Evidence Documents, i.e. CAD results. Medical users are informed about this fact, and not all users use CAD, so this point does not add new risk.
Standardized display of mammography images for all FFDM vendors	Yes	No	Yes	No difference
Intelligent roaming	Yes	Yes		No difference
Can display tomosynthesis images	Yes	Yes	Yes	No difference
Usability				
Single click navigation	Yes	Yes		No difference
Allow instant access to images and shared patient data across multiple workstations	Yes	Yes	Yes	No difference

Conclusion

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The MEDWS Software is substantially equivalent to the predicate software in terms or intended use, indications for use and conformance to the DICOM standard.
The MEDWS software has successfully undergone every bench testing designed to simulate clinical use.
Based on the information supplied in this 510(k), MEDECOM SARL concludes that MEDWS is substantially equivalent to the predicate device and is safe and effective.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 23, 2014

MEDECOM SARL
% Ms. Cynthia Cottereau
Consultant
TWOKSA
2 rue Quenot
JARNAC, 16 200
FRANCE

Re: K132684
Trade/Device Name: MEDWS Software (Variants MEDVIEW, MEDDIAG, MEDMAMMO)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 22, 2014
Received: April 30, 2014

Dear Ms. Cottereau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132684

Device Name
MEDWS software (variants MEDVIEW, MEDDIAG, MEDMAMMO)

Indications for Use *(Describe)*
The MEDWS Software (MEDVIEWS, MEDDIAG, MEDMAMMO) is intended for selection, display, manipulation and media interchange of medical images, including mammograms. It can show images from different modalities and interfaces to various image storage and printing device using DICOM or similar interface standards.

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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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